REMARKS/ARGUMENTS

Regarding the current non-final Office Action of 10/21/2005, Applicant respectfully requests that claims 21 and 23 be amended as indicated above in the Listing of Claims, and that the following remarks and arguments be considered.

Applicant asserts that the claims as amended comply with 37 C.F.R. §1.116 such that they are fully supported in the application as originally filed and contain no new matter, and respectfully request reconsideration for the following reasons.

I. Claim Rejections under 35 USC §§102,103 – rejection of Claims 1-25

Claims 1-25 are rejected under 35 USC §102(b) as anticipated by or, in the alternative, under 35 USC §103(a) as obvious over Depel et al., U.S. Patent No. 4,582,058 ("Depel"). The Office Action asserts that Depel teaches a tracheotomy valve unit comprising all of the elements of claims 1-25, including "a second valve (See Col. 6, lines 63-68 and Col. 7) that permits airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration is greater than about 12 cm of water, and blocks such airflow when the intrathoracic pressure during expiration is less than about 3 cm of water." The current Office actions also assert that, "if Applicant believes that the above recited pressures are not inherent in the teaching of Depel, it should be noted in Col. 5, lines 38-45, Depel teaches that the blow-out/second valve may be predeteminely tuned, i.e., the valve may be set at a certain pressure at which to open and close," such that "it would have been obvious to one of ordinary skill in the art to provide the second valve opening and closing at a certain pressure based on the intended use of the valve."

Applicant asserts that Depel does not disclose, either expressly or inherently, and does not teach or suggest the opening of a second valve during pressures associated with speaking, and in fact teaches that the second valve is closed during speaking. As explained in more detail below, Depel discloses a blow-out/second valve that opens only during substantially increased pressures associated with coughing, which are typically greater than 100 cm of water. Depel does not disclose, teach or suggest opening of the second valve during pressures associated with speaking, which are typically within the ranges disclosed in the present application. Further,

Applicant has amended claims 21 and 23 to more clearly differentiate the present invention from Depel. Specifically, claims 21 and 23 have been amended to require the second valve to begin opening at very low intrathoracic pressures, as described in the specification at page 12, paragraph 45, and at page 9, paragraph 36. Applicant thus respectfully asserts that the claims, as amended, are not anticipated by Depel under 35 USC §102, and are not obvious over Depel under 35 USC §103, for the following reasons.

1. **The Claims, as Amended, are Not Anticipated by Depel under 35 USC §102(b)**

Depel does not anticipate the current invention because Depel not disclose, either expressly or inherently, that the blow-out/second valve can be open during pressures associated with speaking. A claim is anticipated under 35 USC §102(b) "only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 U.S.P.Q.2d (BNA) 1051, 1053 (Fed. Cir. 1987).*

The present Office Action asserts that column 5, lines 38-45 of Depel inherently teaches that the blow-out/second valve "may be predeteminely tuned, i.e., the valve may be set at a certain pressure at which to open and close." (Emphasis added). However, more accurately, column 5, lines 38-45 of Depel states that the blow-out or relief valve "may be predeterminely tuned and sized to open and release the increased air pressure within the valve assembly, and which automatically closes to restore itself when the air pressure within the assembly is reduced therein..." (Emphasis added). Thus, Depel only discloses that the valve is able to open and release upon "increased" air pressure, not at a "certain" pressure. This "increased" air pressure is always attributed in Depel to increased or high air pressure within the valve assembly, such as due to a cough or the like, which is much greater than pressures generated during speaking. In addition, the Abstract of Depel discloses that the blow-out/second valve is in the closed position during speaking: "The valve assembly includes a separate external **relief valve which is closed during** normal vegetative breathing and **speaking**" (Emphasis added). See also Column 7, line 29 to Column 8, line 5 of Depel.

In contrast, the present invention discloses that the second valve is open during pressures associated with speaking, which are typically very low pressures. The Specification discloses that the second valve "begins to open when the intrathoracic pressure during expiration reaches about 3 cm of water, more typically about 4 cm of water, and is fully open when the intrathoracic pressure reaches about 12 cm of water, more typically about 10 cm of water." (See the Specification at page 12, paragraph 45; and at page 9, paragraph 36.) While in the present invention the second valve is typically closed at a pressure less than 3 cm of water, it begins to open at relatively low pressures, typically at pressures greater than 3 cm of water. This is in contrast with the blow-out valve of Depel, which remains closed until increased or high pressures associated with coughing occur. One of ordinary skill in the art will understand that pressures associated with coughing are typically about 100 cm of water or greater, or much higher than 3-12 cm of water. Thus, while Depel may be able to be predeterminely tuned and sized to open upon substantially increased air pressure within the valve, the opening pressures disclosed by the present invention are comparatively very low. Depel cannot be said to have disclosed opening of its blow-out valve at such low pressures.

In addition, claims 21 and 23 have been amended to more clearly differentiate the present invention from Depel. Specifically, claims 21 and 23 have been amended to require the second valve to perform as described in the specification at page 12, paragraph 45, and at page 9, paragraph 36. More specifically, claim 21 as amended requires the second valve to begin to open when the intrathoracic pressure during expiration reaches about 3 cm of water, and is fully open when the intrathoracic pressure reaches about 12 cm of water. This range of pressures will be recognized by one of skill in the art to be much lower than pressures associated with coughing. Claim 23 depends from claim 21, and requires opening of the valve to begin at 4 cm of water and be fully open at 10 cm of water.

Thus, because Depel explicitly states that the relief or blow-out/second valve is closed during speaking and opens only upon pressures associated with coughing, it cannot be maintained that Depel discloses a blow-out/second valve which can be open during the range of pressures disclosed in the present application. It follows then that Depel does not anticipate claims 1-25, as amended, under 35 USC §102(b) because Depel does not disclose each and every

element as set forth in the claims, either expressly or inherently. As such, Applicant respectfully requests that the rejection of claims 1-25 under 35 USC §102(b) be withdrawn.

2. **The Claims, as Amended, are Not Obvious Under 35 USC §103**

The current invention is not obvious over Depel because Depel does not teach or suggest that the blow-out/second valve can be open during pressures associated with speaking, and Depel actually teaches away from a second valve which can be open during pressures associated with speaking. To show a *prima facie* case of obviousness, all claim limitations must be taught or suggested by the reference (or references, when combined). See *In Re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "[A] proper analysis under Sec. 103 requires, inter alia, consideration of . . . whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process." See *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

Rather than teach or suggest the utility of having a blow-out/second valve which can be open during pressures associated with speaking, Depel teaches away from having the blow-out/second valve open during pressures associate with speaking. As noted above, the Abstract of Depel discloses that the blow-out/second valve is in the closed position during speaking: "The valve assembly includes a separate external **relief valve which is closed during** normal vegetative breathing and **speaking**" (Emphasis added). See also Column 7, line 29 to Column 8, line 5 of Depel. Thus, since Depel explicitly states that the relief or blow-out/second valve is closed during speaking, and only opens under substantially increased air pressure, such as due to a cough or the like, it cannot be maintained that Depel teaches or suggests to those of ordinary skill in the art the utility of having a blow-out/second valve which can be open during pressures associated with speaking.

Further, since no other prior art reference has been cited which teaches or suggests an open second valve during pressures associated with speaking, the pressures attributed to Depel are most likely based upon the Applicant's disclosure. To attribute Applicant's disclosed pressures to Depel is impermissible hindsight. "The teaching or suggestion to make the claimed

combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

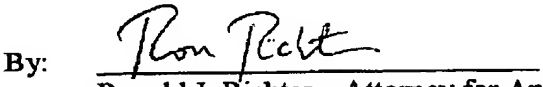
Because Depel teaches a second valve which is closed during pressures associated with speaking, because the above rejection uses hindsight to attempt to show a *prima facie* case of obviousness, and because claims 21 and 23 have been amended to more clearly differentiate the present invention from the prior art, Applicant respectfully requests that the rejection of claims 1-25 under 35 USC 103(a) be withdrawn.

CONCLUSION

Applicant has addressed each point raised in the non-final Office Action dated 10/21/2005 in the present Response. Therefore, Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and remarks, that the rejection of claims 1-25 be withdrawn, and that all the instant claims be duly allowed.

The Examiner is invited to contact the undersigned directly with any questions or remaining issues regarding the pending claims.

Respectfully submitted,
For Applicant MICHAEL J. RUTTER

By: 

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January 13, 2006